IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

TERRI ALLEN IRVIN, Plaintiff, v. BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC and BIOMET MANUFACTURING, LLC, Defendants.	)	Civil Action No. 3:19-00189-MDL **COMPLAINT** ***(Jury Trial Demanded)***

Plaintiff, Terri Allen Irvin, by and through her undersigned counsel, alleges, upon information and belief, the following:

INTRODUCTION

1. For numerous years, Defendants have known that their hip replacement device-the M2a Magnum Hip Replacement System (hereafter, "Magnum Device" or "Device")-is prone to fail years before its expected life. They have also known that the implant's metal "ball" and "socket" bearings that make up the hip-joint generate metal debris over time from wear and tear that can spread throughout the patient's surrounding bone and tissue. As a result of these defects, patients that have had the devices implanted have endured, or will endure, unnecessary pain and suffering; debilitating lack of mobility; inflammation, causing damage or death to surrounding tissue and bone; and a subsequent more difficult revision surgery to replace the faulty devices, giving rise to still more debilitation, a prolonged recovery time, and an increased risk of complications and death from surgery. But rather than recalling the Magnum Device upon receiving notice of complaints made to the United States Food and Drug Administration ("FDA") regarding the defects discussed above, or warning physicians and patients of these risks

and precautions such as metal level monitoring, Defendants continued to aggressively market the Magnum Device, claiming it was a safe and effective hip replacement system. Indeed, Defendants sought to capitalize on the problems with the competitor devices by asserting the superiority of the Magnum.

2. Plaintiff's suffering could easily have been prevented. Plaintiff would not have suffered from unnecessary pain and debilitation, as well as the need to undergo subsequent revision surgery, had Defendants taken the affirmative step of recalling the Magnum Device, when dozens of complaints began being made to the FDA regarding the Magnum Device's failures, or had Defendants at least warned the orthopedic surgical community and the public of the dangers of the Magnum Device so that those who had the Magnum Device implanted could be medically monitored for signs of the Magnum Device malfunctioning including loosening and metal debris related injury. Plaintiff seeks redress for Plaintiff's injuries.

PARTIES

3. Plaintiff Terri Allen Irvin (hereinafter "Plaintiff") is a citizen and resident of Richland County, South Carolina.

4. Defendant Biomet, Inc. is, and at all times relevant herein was, a corporation organized and existing under the laws of the State of Indiana with its principal place of business in Warsaw, Indiana.

5. Defendant Biomet, Inc. designed, manufactured, marketed, promoted and sold the Magnum Device that is the subject of this action and was at all times relevant herein doing business in and/or having directed its activities at South Carolina, and specifically Richland County.

6. Defendant Biomet Manufacturing, LLC is, and at all times relevant herein was, a limited liability company organized and existing under the laws of the State of Indiana with its principal place of business in Warsaw, Indiana. The sole member of Biomet Manufacturing, LLC is Biomet, Inc., an Indiana Corporation with its principal place of business in Warsaw, Indiana.

7. Defendant Biomet Manufacturing, LLC designed, manufactured, marketed, promoted and sold the Magnum Device that is the subject of this action and was at all times relevant herein doing business in and/or having directed its activities at South Carolina, and specifically Richland County.

8. Defendant Biomet U.S. Reconstruction, LLC is, and at all times relevant herein was, a limited liability company organized and existing under the laws of the State of Indiana with its principal place of business in Warsaw, Indiana. The sole member of Biomet U.S. Reconstruction, LLC is Biomet, Inc., an Indiana Corporation with its principal place of business in Warsaw, Indiana.

9. Defendant Biomet U.S. Reconstruction, LLC designed, manufactured, marketed, promoted and sold the Magnum Device that is the subject of this action and was at all times relevant herein doing business in and/or having directed its activities at South Carolina, and specifically Richland County.

10. Defendant Biomet Orthopedics, LLC is, and at all times relevant herein was, a limited liability company organized and existing under the laws of the State of Indiana with its principal place of business in Warsaw, Indiana. The sole member of Biomet Orthopedics, LLC is Biomet U.S. Reconstruction, LLC, an Indiana Corporation with its principal place of business in Warsaw, Indiana.

11. Defendant Biomet Orthopedics, LLC designed, manufactured, marketed, promoted and sold the Magnum Device that is the subject of this action and was at all times relevant herein doing business in and/or having directed its activities at South Carolina, and specifically Richland County.

12. Defendants Biomet, Inc., Biomet Manufacturing, LLC, Biomet U.S. Reconstruction, LLC and Biomet Orthopedics, LLC are collectively referred to herein as the "Biomet Defendants" or “Defendants”.

13. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of each and every other Defendant herein.

14. Upon information and belief, at all times herein mentioned, the employees of all Defendants herein, their subsidiaries, affiliates, and other related entities, as well as the employees of Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such allegations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of Defendants herein committed, knew of, performed, authorized, ratified and/or directed such act or transaction on behalf of Defendants herein while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the Plaintiff and the Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

16. Venue of this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a) as it is the judicial district in which a substantial part of the events or omissions giving rise to the claims alleged herein occurred.

FACTUAL BACKGROUND

17. The Magnum Device was developed in order to reconstruct human hip joints that are diseased due to conditions, such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), or fracture. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

18. A total hip replacement implant device typically consists of four separate components: a femoral stem, a femoral head (or ball), a liner, and an acetabular shell (socket). Usually these components are made of metal and plastic.

19. The Magnum Device has only three components: a metal femoral head, a metal taper insert, and a metal acetabulum cup. The metal femoral head can be attached to a femoral stem to complete a total hip replacement. As a result of the use of metal in the ball, taper insert, and socket components, the device is referred to by the industry as a Metal-on-Metal (MoM) Implant Device.

20. These devices were marketed with the claim that they would last much longer than the conventional hip implant with a polyethylene liner. Indeed, Defendants aggressively marketed the Magnum Device as having many advantages over other hip replacements or hip resurfacing systems.

21. When initially released, Defendants promoted the device to surgeons as being "designed specifically to address the issue of wear debris" and held it out as "the right choice for use in young, highly active patients."

22. Later, Defendants promoted the device as "offering improved range of motion and joint stability" and employed gymnast, Mary Lou Retton, to deliver the message in April 2006 for direct-to-consumer print, TV, and radio advertising.

23. Even as other MoM devices came under scrutiny for their high rates of failure over the years, Defendants continued to falsely advertise the Magnum Device as a superior and safe device, citing biased and misleading studies and data indicating that the hip replacement was subject to reduced wear and revision.

24. Contrary to what Defendants' marketing campaigns suggest, for many years Defendants have known of the risks inherent in MoM devices, including the Magnum Device and its predecessor metal on metal large diameter implant, the M2A 38, which were causing harm in a high number of patients who received them. Specifically, for several years, the FDA had been receiving complaints that the Magnum Devices prematurely failed in some patients, due to component loosening, dislocation, component wear, and fracture, as a result of the design of the device. In addition, reports were received that the implant's "ball" and "socket"—which are both metal bearings—generate metal debris over time from normal wear, and this debris can spread throughout the surrounding bone and tissue causing severe inflammation and damage to patients such as Plaintiff herein.

25. Indeed, since the start of 2006, the FDA has received an increasing number of complaints involving patients in the United States that received the Magnum Devices, with a number of these patients requiring complicated, expensive and painful revision surgeries with a

prolonged recovery time. Notwithstanding these complaints, Defendants neither halted sales of the Magnum Device nor warned the public. Instead, they continue to aggressively market the Magnum Device as safe and effective, even though they were on notice of the large number of complaints received by the FDA.

26. Defendants were aware that the British Medicines and Healthcare Products Regulatory Agency (MHRA) and the United States Food and Drug Administration expressed concern about Metal-on-Metal hips and the impact of metal ions and thus Defendants, as part of industry trade groups, participated in discussion of studies of the health effects with other manufacturers during that time period.

27. Despite its knowledge that the Magnum Device was defective, Defendants made several false representations about specific design elements of the Magnum Device that they claimed made it superior to other more safe hip implants on the market. For example, Defendants claimed that:

(a) "The M2a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo," and

(b) "Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

28. Defendants' reasons for concealing defects in the Device are clear, as hip implant sales are critically important to Defendants. During the time period relevant to this action and Defendants' manufacturing and marketing of the Device, Defendants' management was trying to make Defendants look appealing to investors.

29. In fact, in 2007, Defendants were ultimately purchased by a private equity firm for $10 billion. At that critical time, Defendants were faced with defects in one of its most

profitable hip implant systems, a problem that, if it were discovered or disclosed at that time, would have had significant financial ramifications for Defendants.

30. Rather than to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery, Defendants chose to pursue corporate profits, at the expense of patient safety, and continued to promote, market, and sell the Magnum Device despite the fact that they knew the product was defective. To this day, Defendants continue to sell these defective implants to unsuspecting patients without any warning about defective nature of the product, the safety risks to patients, or the excessive rates of failures of the Device that have been reported to Defendants.

31. In 2011, the Australian Orthopedic Association published its annual report on data collected from the Australian National Joint Registry, which tracks surgical revisions of orthopedic devices in Australia (the United States does not have such a registry). The Report showed that the Magnum Device had a yearly cumulative revision rate of 7.2% after seven years, with a statistical range of 5.3% and 9.7%. This is a much higher revision rate than some other MoM hip replacements.

32. Consequently, in May of 2011, the FDA required Defendants, and other manufacturers, to provide data on levels of metal in the blood of patients implanted with their MoM hip implants due to rising concerns regarding their use. The FDA's request followed the release of British studies from March 2010 showing that MoM hip implants, such as the Magnum Device, are potentially dangerous because they can generate large amounts of metallic debris that is absorbed into patients' bodies as they wear over time. Metallic debris has been shown to cause severe inflammatory responses in some patients, resulting in pain in the groin,

death of tissue in the hip joint, and loss of surrounding bone. These injuries often require revision surgery to replace the device before its expected expiration.

33. In a systematic review of clinical trials, observational studies, and registries conducted by the FDA and published in the *British Medical Journal* on November 29, 2011, it was found that MoM hip implants are no more effective than traditional polyethylene-lined implants, and that metal-on-metal hip implants are associated with an increased risk of patients requiring revision surgery. In other words, these studies show that metal-on-metal hip implants, such as the Magnum Device manufactured and marketed by Defendants and implanted in Plaintiff's body, increase the safety risks for patients without providing any benefits over traditional hip implants.

34. Following dissemination of this data and information on this poor risk-versus-benefit profile for metal-on-metal hip implants, sales of the Magnum Device have decreased substantially.

35. As a result of the issues with the Magnum Device, Plaintiff has suffered symptoms including pain, swelling, inflammation, and damage to surrounding bone and tissue, and lack of mobility. As noted above, these symptoms are the result of loosening of the implant, where the implant pulls away from the bone of the hip socket; fracture, where the bone around the implant may have broken; dislocation, where two parts of the implant that move against each other are no longer aligned; and the spread of metal debris generated from wear of the metal femoral head and metal acetabular cup. For these reasons, revision surgery is necessary to remove the defective Magnum Device. Revision surgery presents enormous risks because it is technically more difficult than the original implanting surgery, the patient has an increased risk

of complications and death, and the recovery time is prolonged and more painful than the recovery after the original implanting surgery.

36. On March 11, 2014, Plaintiff underwent a left total hip arthroplasty surgery performed by Coleman Fowble, M.D. at Palmetto Health Baptist in Columbia, South Carolina and received a Magnum Device.

37. Subsequent to surgical recovery and thereafter, Plaintiff suffered symptoms including but not limited to increasing pain, discomfort, dysfunction, soreness and loss of range of motion.

38. On May 11, 2016, Plaintiff was required to undergo revision surgery, which was performed by Thomas Gross, M.D. at Providence Hospital in Columbia, South Carolina to replace the failed Magnum Device.

39. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

40. An employee and/or agent of Defendants provided the Magnum Device to Plaintiff's original implanting surgeon at the time of the original surgery to implant the Device as noted herein.

41. Beyond merely providing the Magnum Device to the surgeon, agents of Defendants were hired by Defendants to aggressively promote, distribute, and sell the Magnum Device.

42. Directors, managers, and sales representatives of Defendants received training and education from Defendants, including orthopedic and surgical training, product design rationale for the Magnum Device, education regarding proper use of the tools to implant the

Magnum Device, selection of complementary components to the Magnum Device, and training on how to sell the Magnum Device to surgeons over hip replacements offered by competitors.

43. On numerous occasions, Defendants met with orthopedic surgeons, including, on information and belief, with Plaintiff's orthopedic surgeon who performed the original implantation surgery on Plaintiff, to promote the Magnum Device.

44. At some or all of these meetings, a representative or representatives of Defendants were present. During these meeting, Defendants assured the orthopedic surgeons, including (upon information and belief) Plaintiff's original implanting orthopedic surgeon, that the Magnum Device was safe, effective, was the best product on the market, had an excellent track record, would last longer than traditional hip implants and had a low and acceptable failure rate.

45. Defendants continued to "defend" the Magnum Device even after they became aware of numerous and serious complications with the Device. Further, Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons, including Plaintiff's original implanting orthopedic surgeon.

46. Plaintiff's revision surgery has subjected her to much greater risks of future complications than she had before the revision surgery. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4% of patients who underwent a revision surgery suffered from a dislocation compared with 3.9% of patients who underwent a original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips

CB, *et al.* Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

47. Upon information and belief, Defendants were instrumental in educating Plaintiff's original implanting orthopedic surgeon regarding claimed advantages of the product, addressing the questions of the surgeon and providing information that the surgeon could, in turn, share with patients such as Plaintiff herein who were contemplating hip implant surgery and making decisions regarding the type of product to be utilized for such a procedure.

48. Had Plaintiff or Plaintiff's surgeon known that the Magnum Device caused injury, posed serious safety risks, that its risks outweighed its benefits, that far safer and reliable alternatives were available, and/or the likelihood of premature device failure and the need for early revision surgery to remove the defective Magnum Device, neither Plaintiff and/or Plaintiff's original implanting surgeon would have chosen the Magnum Device for the initial hip implant surgery. Rather, Plaintiff and/or Plaintiff's original implanting surgeon would have opted for the safer and more effective traditional hip implant models.

49. As a direct and proximate result of Defendants placing the defective Magnum Device into the stream of commerce, Plaintiff has suffered, and continues to suffer, injuries and damages including, but not limited to, the following: past, present, and future physical and mental pain and suffering; past, present, and future expenses for medical, rehabilitation, and nursing care; loss of earnings and the capacity to earn a living; and loss of the quality of life. These injuries and damages are continuing.

FOR A FIRST CAUSE OF ACTION
(Strict Products Liability – Design Defect)

50. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

51. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Magnum Device as hereinabove described that was surgically implanted in Plaintiff.

52. At all times herein mentioned, the Magnum Device was in an unsafe, defective, and inherently dangerous condition for users such as Plaintiff who had the device surgically implanted.

53. The Magnum Device was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

54. At all times herein mentioned, the Magnum Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

55. The Magnum Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff.

56. The Magnum Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

57. Plaintiff's injuries resulted from use of the Magnum Device that was both intended and reasonably foreseeable by Defendants.

58. At all times herein mentioned, the Magnum Device posed a foreseeable risk of danger inherent in the design which greatly outweighed the benefits of that design.

59. At all times herein mentioned, the Magnum Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

60. At all times herein mentioned, the Defendants knew, or should have known, that the Magnum Device was in a defective condition, and was and is inherently dangerous and unsafe.

61. At the time of the implantation of the Magnum Device into Plaintiff, the aforesaid product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

62. Defendants, with this knowledge, voluntarily designed their Magnum Device in a dangerous condition for use by the public and, in particular, Plaintiff.

63. Defendants had a duty to Plaintiff and other patients to create a product that was not unreasonably dangerous for its normal and intended use.

64. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, including Plaintiff herein, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff as a result of implantation of the defective Magnum Device.

65. As a direct and proximate result of Defendants' placement of the defective Magnum Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk

of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

66. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

67. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

FOR A SECOND CAUSE OF ACTION
(Strict Products Liability – Failure to Warn)

68. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

69. At all times herein mentioned, Defendants designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Magnum Device that was surgically implanted in Plaintiff herein.

70. The Magnum Device was defective due to inadequate warnings, as Defendants knew or should have known that the Device could fail early in patients, including Plaintiff herein, and therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery, but failed to give consumers, such as Plaintiff, adequate warning of such risks.

71. The Magnum Device is unsafe and inherently dangerous due to inadequate warnings because it was sold to Plaintiff without adequate warnings regarding the following unsafe conditions, propensities, and risks of the Device: to loosen and cause serious pain and necessitate additional surgery; to generate metal debris resulting in metallosis and increased cobalt and chromium levels; to cause damage to soft tissue and bone; to subject the patient to possible cancer and other potential harm due to elevated metal ions and metallosis.

72. The Magnum Device was defective, unsafe, and inherently dangerous due to inadequate warnings at the time that it left Defendants' possession and was placed into the stream of commerce.

73. At all times herein mentioned, the Magnum Device and its associated instructions and warnings were expected to and did reach the usual consumers, handlers, and persons coming into contact with said product, including Plaintiff herein, without substantial change in the condition in which the Device and its associated instructions and warnings were designed, produced, manufactured, sold, distributed, and marketed by Defendants.

74. The Magnum Device's unsafe, defective, and inherently dangerous condition due to inadequate warnings and instructions were the cause of injury to Plaintiff herein, and those injuries were reasonably foreseeable by Defendants.

75. As a direct and proximate result of Defendants' placement of the Device with its inadequate and defective warnings and instructions for use into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need

for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

76. Further, as a result of the foregoing defects in the instructions and warnings that accompanied the Device, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

77. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

FOR A THIRD CAUSE OF ACTION
(Breach of Express Warranty)

78. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

79. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Magnum Device as hereinabove described that was surgically implanted in Plaintiff.

80. Defendants expressly warranted that the Magnum Device was a safe and effective hip replacement system and that it would last longer than a traditional polyethylene lined implant and was thus appropriate for young and active patients.

81. Indeed, as set forth in detail above, Defendants made numerous representations about the quality, safety, effectiveness and expected lifetime of the Magnum Device which form express warranties.

82. The Magnum Device placed into the stream of commerce by Defendants did not conform to these express representations because they failed early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Magnum Device with the attendant risks of complications and death from such further surgery.

83. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Magnum Device, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

84. Further, as a result of the foregoing acts and omissions and breach of express warranties, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

FOR A FOURTH CAUSE OF ACTION
(Violation of the South Carolina Unfair Trade Practices Act)

85. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

86. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Magnum Device as a high-quality, safe and effective hip replacement system to Plaintiff and Plaintiff's original implanting surgeon.

87. Before they advertised, marketed, sold and represented the Magnum Device that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers

and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiff.

88. Plaintiff purchased and used the Magnum Device for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

89. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Magnum Device, and would not have incurred related medical costs and injury.

90. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Magnum Device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

91. Unfair methods of competition or deceptive acts or practices that were prescribed by law, including the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

92. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Magnum Device. Each aspect of Defendants' conduct combined to artificially create sales of the Magnum Device.

93. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion and sale of the Magnum Device.

94. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Magnum Device, and would not have incurred related medical costs.

95. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes, as listed below.

96. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

97. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the South Carolina Unfair Trade Practices Act, S.C. Code §39-5-10, *et seq.*

98. These acts and/or omissions are a violation of the South Carolina Unfair Trade Practices Act, S.C. Code §39-5-10, et seq., as these acts and/or omissions occurred during act(s) of business affecting trade or commerce in South Carolina.

99. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

100. Defendants violated the statutes that were enacted in this state to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Magnum Device was fit to

be used for the purpose for which it was intended, when in fact the Magnum Device was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

101. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

102. Defendants had actual knowledge of the defective and dangerous condition of the Magnum Device and failed to take any action to cure such defective and dangerous conditions.

103. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which hip implant device to use and recommend.

104. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

105. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

106. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

107. As specifically described in detail above, Defendants knew that the Magnum Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

108. The Defendants' actions are not in the public interest and directly as well as indirectly negatively impact the public interest.

109. As a direct and proximate result of Defendants' representations, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis. Further, as a result of the foregoing, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

110. The possibility that these acts may in the future be repeated by the Defendant with other South Carolina residents or business is an impact upon the public interest which must be protected.

111. The Plaintiff is entitled to all remedies available under the South Carolina Unfair Trade Practices Act including but not limited to actual damages, treble damages, attorneys' fees, costs, and punitive damages.

FOR A FIFTH CAUSE OF ACTION
(Negligence)

112. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

113. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, selling, testing, assuring quality and/or distributing the Magnum Device into the stream of commerce, including a duty to assure that the Device would not cause patients in whom the Device was surgically implanted, such as Plaintiff herein, to suffer harmful effects and injuries caused by the Device.

114. Defendants failed to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, selling, testing, assuring quality and/or distributing the Magnum Device into the stream of commerce in that Defendants knew or should have known that patients who were surgically implanted with the Device, including Plaintiff herein, were at risk for suffering harmful effects and injuries caused by the Device including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

115. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Negligently designing the Magnum Device in a manner which was dangerous to those individuals who had the Magnum Device surgically implanted, including Plaintiff herein;

(b) Designing, manufacturing, producing, creating, and/or promoting the Magnum Device without adequately, sufficiently, or thoroughly testing it;

(c) Failing to conduct sufficient testing programs to determine whether or not the aforesaid Magnum Device was safe for use in patients such as Plaintiff herein;

(d) Failing to inform patients, including Plaintiff herein, and surgeons, including Plaintiff's original implanting surgeon, that the Magnum Device was unsafe and unfit for use due to its defective condition, inherently dangerous, dangerous beyond the extent that would be contemplated by an ordinary consumer with ordinary knowledge as to the Magnum Device's characteristics, and the fact that the risks of use of the Magnum Device outweighed the Device's benefits;

(e) Selling the Magnum Device without making proper and sufficient tests to determine the dangers that the Device posed to patients, including Plaintiff herein;

(f) Negligently failing to adequately and correctly warn Plaintiff or Plaintiffs physicians, hospitals and/or healthcare providers of the dangers of Magnum Device;

(g) Negligently failing to recall their dangerous and defective Magnum Device at the earliest date that it became known that the Device was, in fact, dangerous and defective;

(h) Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Magnum Device into their patients;

(i) Negligently advertising and recommending the use of the Magnum Device despite the fact that Defendants knew or should have known of its dangerous propensities;

(j) Negligently representing that the Magnum Device was safe for use for its intended purpose, when, in fact, it was unsafe;

(k) Negligently manufacturing the Magnum Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

(l) Negligently producing the Magnum Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

(m) Negligently assembling the Magnum Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

(n) Under-reporting, under-estimating, and downplaying the serious dangers associated with use of the Magnum Device;

(o) Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the Magnum Device in that they failed use due care in designing and manufacturing the Device so as to avoid the aforementioned risks to patients who had the Magnum Devices surgically implanted, including Plaintiff herein;

(p) Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the Magnum Device in that they failed to accompany the Device with proper warnings and instructions for use;

(q) Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the Magnum Device in that they failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Device;

(r) Acting with willful, reckless and wanton misconduct in allowing the dangerous and defective Magnum Device to be implanted in patients, including Plaintiff herein, without sufficient testing and with express knowledge of enhanced risks, and

(s) Otherwise acting with careless and/or negligent disregard for the health and safety of patients, including Plaintiff herein.

116. Despite the fact that Defendants knew or should have known that the Magnum Device caused harm to patients in whom the Device was surgically implanted, including Plaintiff herein, Defendants continued to market, manufacture, distribute, and/or sell the defective and unreasonably dangerous Magnum Device.

117. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

118. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and the economic losses which Plaintiff has suffered and/or will continue to suffer.

119. As a direct and proximate result of Defendants' failure to exercise ordinary care and negligent acts as outlined above with regard to placement of the defective Magnum Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to

revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

120. Further, as a result of the foregoing failure to exercise ordinary care and negligent acts of Defendants, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

121. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

FOR A SIXTH CAUSE OF ACTION
(Negligent Misrepresentation)

122. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

123. Defendants supplied false information to the public, to Plaintiff and to Plaintiff's physicians regarding the high-quality, safety and effectiveness of the Magnum Device. Defendants provided this false information to induce the public, Plaintiff and Plaintiff's original implanting surgeon to purchase and implant a Magnum Device.

124. Defendants supplied through their sales brochures, false information to the public, to Plaintiff and to Plaintiff's original implanting surgeon regarding the high-quality, safety and effectiveness of the Device, including, statements of low wear, excellent stability, optimal clearance, 99.2% survivorship rate, revision rates of less than 2.5% and superiority over other metal-on-metal hip implants. Defendants provided this false information to induce the public,

Plaintiff and Plaintiff's original implanting surgeon to purchase and implant an M2a Magnum Device.

125. Defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the implant would induce Plaintiff and Plaintiff's original implanting surgeon to purchase and use a Magnum Device was false and misleading.

126. Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Magnum Device.

127. Plaintiff and Plaintiff's original implanting surgeon relied on the false information supplied by Defendants to Plaintiff's detriment by causing the Magnum Device to be purchased and implanted in Plaintiff.

128. Plaintiff and Plaintiff's original implanting surgeon were justified in their reliance on the false information supplied by Defendants regarding the purported high-quality, safety and effectiveness of the Magnum Device.

129. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

130. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

131. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

FOR A SEVENTH CAUSE OF ACTION
(Breach of Implied Warranty of Merchantability)

132. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

133. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device.

134. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device, Defendants knew the use for which the Magnum Device was intended, and impliedly warranted the Magnum Device to be of merchantable quality.

135. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Magnum Device was of merchantable quality.

136. Contrary to Defendants' implied warranties, the Magnum Device was not of merchantable quality or safe for the ordinary purposes for which it was to be used, because the Magnum Device was unreasonably dangerous and/or not reasonably fit for its intended, anticipated or reasonably foreseeable use as described above.

137. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the Magnum Device, Plaintiff experienced and/or will

experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

138. Further, as a result of the foregoing acts and omissions and breach of implied warranties, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

139. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

FOR AN EIGHTH CAUSE OF ACTION
(Breach of Implied Warranty of Fitness for a Particular Purpose)

140. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

141. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device.

142. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device, Defendants knew the use for which the Magnum Device was intended, and impliedly warranted the Magnum Device to be of safe for such use.

143. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Magnum Device was safe for its intended use.

144. Contrary to Defendants' implied warranties, the Magnum Device was not of safe for its intended use or fit for the particular purpose for which it was designed, manufactured, tested, distributed or sold - for use and implantation as a total hip replacement system, because the Magnum Device was unreasonably dangerous and/or not reasonably fit for its intended, anticipated or reasonably foreseeable use as described above.

145. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the Magnum Device, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

146. Further, as a result of the foregoing acts and omissions and breach of implied warranties, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

147. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, having fully set forth her Complaint above, the Plaintiff prays for judgment against the Defendants, jointly and severally, for a sum of actual and punitive damages found to be fair, just, and proper; for the costs of this action; and for such other and further relief as this Court may deem just and proper.

Respectfully submitted this 22nd day of January, 2019.

WALKER MORGAN, LLC

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